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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/568,712

08/08/2007

Irmgard Gergely

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07/12/2010

ROTHWELL, FIGG, ERNST & MANBECK, P.C.

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SUITE 800

WASHINGTON, DC 20005

EXAMINER

AHMED, HASAN SYED

ART UNIT

PAPER NUMBER

1615

NOTIFICATION DATE

DELIVERY MODE

07/12/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No. 10/568,712	Applicant(s) GERGELY ET AL.	
	Examiner HASAN S. AHMED	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-23 and 25-68 is/are pending in the application.
- 4a) Of the above claim(s) 18-21, 32-34, 52-56, 67 and 68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17, 22, 23, 25-31, 35-51 and 57-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/25/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicants' response, filed on 12 February 2010; and IDS, filed on 25 April 2008.

* * * * *

Election/Restrictions

Applicants' election with traverse of Group I in the reply filed on 12 February 2010 is acknowledged. Applicants arguments are persuasive; as such, Groups I-IV from the restriction requirement mailed on 30 February 2009 are hereby rejoined.

Claims 18-21, 32-34, 52-56, 67 and 68 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12 February 2010.

* * * * *

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 (b) as follows: Applicant failed to provide an English translation of the foreign application AUSTRIA A 1309/2003. As such, the priority date of the instant application is interpreted as 7 August 2004, which is the date of PCT/EP04/08879.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-17, 22, 23, 25-31, 35-51, and 57-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,911,930 ("Gergely '930").

Gergely '930 teaches granulation of an effervescent mixture in a vacuum maintained at between 600-900 mbar (see col. 2, lines 58-63).

Regarding claims 1, 12-14, 30, 35, 46-49, 58, 64, 65, and 66, Gergely '930 teaches treatment of a pharmaceutically active substance (e.g. paracetamol, naproxen, etc.; see col. 4, line 53) and a binding agent with water by application of vacuum (see col. 4, lines 5-9). For each of the programmed operating modes, only three control means need be provided: the inflow valve for the pre-adjusted water vapor-air mixture, the valve to the vacuum pump for changing from a low constant vacuum for the condensation to a full vacuum for drying, and the control to regulate the agitation rate during condensation and drying (see col. 4, lines 9-19; example 7). Cycle times can be varied depending upon the product to be treated (see col. 4, lines 49-50; example 7). Particulate process material may be introduced into a vacuum chamber to agitate the process material (see col. 6, lines 17-23; example 7). It is necessary to control the difference in pressure between the hot air inflow and the extraction in the vacuum phase (see col. 4, lines 58-60).

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Example 7 describes production of a reactive product suitable for effervescent preparations. Citric acid is heated in a vacuum mixing drum followed by introduction of calcium carbonate. Residual moisture is evacuated. Then, a constant vacuum of 600-900 mbar is generated in the vacuum mixing drum. The pumps and valves are adjusted such that at 700 mbar, about 600 to 800 liters of hot air can flow into the process chamber per minute. 500 ml of water is allowed to flow within 2 minutes out of the tank and into the heat exchanger (see col. 13, lines 45-68). Carbon dioxide is produced and extracted via vacuum pump (see col. 14, lines 1-4). The control valve, which is controlled by a pressure valve and generates a vacuum of e.g. 700 mbar in the process chamber is closed at the selected time of the program such that the pump brings the process chamber up to full vacuum (see col. 14, lines 50-54). If the valve is opened again, an amount of, e.g., 500 ml water is fed into the process chamber within a selected time unit of, e.g., 2 min. When this time has elapsed, the valve is closed and after a further 60 seconds, the valve is opened to reach full vacuum. When the vacuum in the process chamber has reached an end value of, e.g., 20 mbar, the cycle can be repeated. After two or three cycles, the process chamber can be held for about 15 minutes at values of below 10 mbar for the concluding drying of the process material (see col. 14, lines 55-68).

Regarding claims 16, 17-20, 22, 31, and 50, carbon dioxide may be used for gas flow (see col. 5, line 13; example 7).

Regarding claims 11, 23, 28, 45, 57, and 63, water may be used as a treatment agent (see col. 6, lines 55-58; example 7).

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Regarding claims 2, 3, 10, 25, 28, 26, 36, 37, 44, 59, 60, and 62, when water is used as the treatment agent, the condensation on the typically 50 degrees C warm process material takes place at about 200-800 mbar and evaporation is at nearly the same process material temperature and 10-30 mbar pressure in the process chamber (see col. 6, line 64 – col. 7, line 2; example 7).

Regarding claims 4-9, 27, 38-43, and 61, the air temperature and cycle times can be varied depending on the product to be treated (see col. 4, lines 49-50). The cycle time can be controlled and the process can be terminated by continuous moisture treatment. With pressure reduction, the treatment agent removal phase that can effect partial or almost complete removal of the treatment agent will start and lasts 30 sec. to 30 min. (see col. 8, lines 1-6). The treatment is performed in more than one cycle, preferably in five or more cycles, until a specific end condition has been achieved (see col. 8, lines 7-14; example 7).

Gergely '930 differs from the instant application in that it does not explicitly teach the vacuum range recited in claim 1. However, Gergely '930 teaches that vacuum is maintained at between 600-900 mbar (see, e.g., col. 2, lines 62-63). In the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a method of producing effervescent granules with an acidic and an alkaline component by applying a cyclical vacuum, as taught by Gergely

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'930, et. al. One of ordinary skill in the art at the time the invention was made would have been motivated to use such a method because it results in uniform treatment and uniform distribution of treatment agents, as explained by Gergely '930 (see col. 6, lines 8-16).



Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/H. S. A./
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615

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